Food-related quality of life in inflammatory bowel disease: development and validation of a questionnaire

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ABSTRACT

Background and aims

Psychosocial factors surrounding eating and drinking such as enjoying food, managing restrictions and maintaining social relationships remain under-researched in IBD. This study aimed to develop and validate a food-related quality of life (FR-QoL) questionnaire to systematically measure these issues in the IBD population.

Methods

Following semi-structured interviews with 28 IBD patients, 150 potential questionnaire items were generated. These were ranked by 100 IBD patients and items were removed based on ceiling/floor effects and high inter-item correlations (>0.7), with 41 items being retained. In total, 323 IBD patients, 100 asthma patients (chronic disease control) and 117 healthy controls completed the FR-QoL questionnaire alongside generic and disease-specific QoL and food satisfaction questionnaires. Principle components analysis (PCA), construct and discriminant validity and test-retest reliability were calculated.

Results

Twelve items were removed following PCA. The reduced questionnaire (FR-QoL-29) explained 63.9% of the variance (Cronbach's α=0.96). FR-QoL-29 correlated significantly with generic QoL (r=0.697), depression (r=-0.519), anxiety (r=-0.531) and food satisfaction (r=0.701). The FR-QoL-29 sumscores were significantly lower for IBD (89.5, SD 28.6) than asthma (125.4, SD 24.1); p<0.001) and healthy volunteers (123.0 (SD 16.5); p<0.001). Within IBD, worse food-related QoL was found in those with moderate/high disease activity (66.7, SD 22.1) compared to remission/low disease activity (92.5, SD 28.1). Test-retest reliability was good (ICC=0.83, 95% CI=0.76:0.88).

Conclusions

The FR-QoL-29 shows good reliability and validity across a range of IBD characteristics. This easily administered questionnaire is a useful tool in identifying poor food-related QoL and in the future may identify areas for intervention.

INTRODUCTION

Inflammatory bowel disease (IBD) is associated with a significant negative impact on quality of life (QoL) both during relapse and remission[1-3]. Poor QoL and psychological distress are related to, among others; active gastrointestinal and systemic symptoms,[1, 4] embarrassment[5] and social impairment[4]. Despite this, almost half of patients with IBD report that their doctor does not ask about the impact of their disease on QoL[3].

Malnutrition is a common consequence of IBD[6] and contributes to poor QoL[7, 8]. However, in IBD, access to information regarding diet and nutrition is variable[9], addressed by clinicians in a minority of patients[10] and focuses more on specific issues such as enteral nutrition[10-12] rather than ongoing nutritional management or psychosocial impacts. Meanwhile, there is growing evidence that IBD has a significant impact on the psychosocial aspects of food, termed food-related QoL which encompasses achieving adequate nutrition, deriving pleasure and maintaining social activities through eating and drinking [13-16].

Although evidence supporting the role of food and drink in IBD aetiology and symptom exacerbation is mixed[17], patients have strong beliefs about the role of "trigger foods/drinks". In response many patients make substantial dietary changes [18, 19], including omitting specific foods/food groups [20, 21] or severely restricting the quantities consumed[14, 20], as coping mechanisms to address the "lifelong struggle" of knowing what to eat[22, 23]. Consequently, patients with IBD can feel excluded from social interactions involving eating and drinking, resulting in stress and anxiety[14, 24, 25], alienation from friends and family[24] and guilt at letting others down[14, 20]. The impact of food restriction and social withdrawal has particular relevance in IBD where diagnosis often occurs in young adulthood when patients are forming new relationships and building careers. Social isolation may contribute to the high rates of depression and anxiety in people with IBD[26, 27].

Despite these numerous qualitative studies demonstrating profoundly impaired food-related QoL in IBD, no study has formally assessed the prevalence of these issues or whether targeted intervention can reduce its impact. This is undoubtedly due in part to the lack of a valid and reliable tool to measure food-related QoL in IBD. Although numerous tools are available to screen for malnutrition risk[28], only a small number of questionnaires measure the broader psychosocial aspects of eating and drinking, none of which are specific to IBD.

The aim of this study was to develop and validate a food-related QoL questionnaire specifically for patients with IBD. A reliable and valid tool that quantifies this phenomenon could be used to measure the prevalence of such problems and to develop and evaluate interventions to address them.

MATERIALS AND METHODS

Development of the questionnaire

Questionnaire items were generated from semi-structured interviews relating to the psychosocial aspects of eating and drinking among 28 people with IBD[14]. Verbatim quotes were reviewed by a steering group consisting of a gastroenterologist, dietitians, a medical sociologist and a psychologist to remove items of low relevance to the phenomenon under investigation, to remove duplicate statements and to ensure that the wording of the items was appropriate. Three people with IBD, one gastroenterologist, one IBD specialist nurse and one health psychologist outside of the research team reviewed the items for readability and small changes were made to aid comprehension.

In order to reduce the number of potential items and to include only those that were of most importance, 100 patients with a confirmed diagnosis of IBD were recruited consecutively from routine out-patient appointments at IBD clinics in hospitals across London, UK and were asked to rate each statement as to:

(i) whether the issue had been important to them in the past two weeks; and

(ii) the strength of importance on a five point Likert-type scale.

An overall "importance score" for each potential item was calculated by multiplying the proportion of patients indicating that the item was important (i) by the mean strength of importance (ii)[29, 30]. Ceiling and floor effects were investigated and items were removed if ≥80% of patients responded with the minimum or maximum "importance score"[31]. Inter-item correlations were calculated for the "importance score" and items with correlations of ≥0.8 were discussed by the steering group and the item considered to have the best face validity was retained.

In line with other quality of life measures (e.g. the UK IBD-Q[32]), a two week reference point for the food-related QoL questionnaire was used with a five point Likert-type response scale ranging from 1 (*definitely agree*) to 5 (*definitely disagree*). Questions were phrased such that higher scores indicate better food related quality of life.

Validation of the questionnaire

A separate sample of IBD patients was recruited consecutively from gastroenterology and specialist IBD outpatient clinics covering urban (London, UK) and suburban (South East, UK) areas. Efforts were made to sample the entire range of clinical disease by targeting clinics for both adult and adolescent IBD and pre- and post-surgery clinics. Inclusion criteria included any patient with a confirmed diagnosis of IBD aged ≥16 years who was able to read English and provide informed consent. Patients with either active or inactive disease were included. Exclusion criteria were limited to conditions that might impact on normal eating behaviour (e.g. currently pregnant or breastfeeding; diagnosed eating disorder; current exclusive parenteral or enteral nutrition; or an acute illness in the past month such as common cold, influenza, gastroenteritis) and those that might impact on quality of life (e.g. severe mental illness).

Clinical information extracted from medical notes included diagnosis (CD, UC), date of diagnosis, and surgery status (no surgery, previous surgery). Disease phenotype (Montreal classification), disease activity (Harvey-Bradshaw index for CD[33], Partial Mayo Score for UC[34]) and body mass index (BMI) were recorded prospectively. Participants completed the newly developed food-related quality of life (FR-QoL) questionnaire. In addition, they completed the Satisfaction with Food-related Life Questionnaire (SWFL[35]); the Hospital Anxiety and Depression Scale (HADS[36]); The SF-36[37] (general quality of life, recalled

over the past four weeks); the UK IBD-Q[32] (disease-specific quality of life); and the MUST Nutritional Risk Questionnaire[38] (high, medium or low risk of malnutrition).

A healthy volunteer control group was recruited as well as a chronic illness control group comprising patients with asthma. Asthma was chosen as the chronic illness control to ensure that any differences found in responses by IBD patients were specific to the condition itself, rather than to having any long term condition[39]. Participants in both control groups were ≥16 years old, able to read English, consent for themselves and able to eat independently. The same exclusion criteria as for the IBD group applied with the additional criteria that the control participants had not experienced digestive symptoms in the past month or been diagnosed with a gastrointestinal illness at any time. Healthy volunteers were recruited via a circular email to staff and students of a university in the same geographical location and subsequent snowballing. People with asthma were recruited both through circular email to staff and students of the same university and from specialist asthma clinics, in order to recruit a range of disease severity and geographic location comparable to the IBD sample. Control participants completed the same questionnaires as IBD patients with the exception of disease-specific quality of life. The asthma group completed the Asthma Control Questionnaire[40] and the healthy volunteers completed the SF-36[37] only.

Local NHS research ethics committee approval was obtained before conducting the study. Participants were only recruited after informed consent.

Psychometric analysis of the questionnaire

All statistical analysis was performed using SPSS v20 (IBM, United States).

The underlying factor structure of the questionnaire was identified using Principal Components Analysis (PCA) with varimax rotation on the FR-QoL data from IBD patients.

PCA is a statistical technique identifying which items fit together to create latent "factors" and which items explain the most variance within the scale[41, 42]. Factors were considered important if their Eigen value >1.2 and items that did not have a factor loading of at least 0.4 were considered for removal as this indicates that they were not measuring the intended phenomenon i.e., food related QoL[41].

Internal consistency relates to whether all items of the scale are reliably measuring the same construct. This is assessed by correlating each item with every other item. The test statistic, Cronbach's α, should exceed 0.7 for good internal consistency[43].

Concurrent validity was established by correlating the FR-QoL sumscore with the IBD-Q[32], SF-36[37], HADS[36] and SWFL[35] as these separate questionnaires were determined to be measuring similar constructs as the FR-QoL and are well validated. Pearson's r correlation co-efficient should be in the order of 0.7 to indicate that the FR-QoL questionnaire is measuring a similar construct to these validated questionnaires but that there are differences to justify a new measure[44].

Discriminant validity of the questionnaire was assessed using the "known groups" method[45] to determine if the questionnaire differentiates between groups that are theoretically expected to differ *a priori*[46]. The healthy volunteer and asthma control groups are expected to score better on FR-QoL than the IBD group. This was analysed using ANOVA with Bonferroni adjustment to reduce Type I error. In addition, IBD patients with low disease activity are expected to score better than those with high disease activity; these two groups were compared via t-test.

Test-retest reliability was assessed by requesting the first 100 patients with IBD to complete the FR-QoL again four weeks later. However, patients were excluded from this analysis if during the four week period, they self-reported that their IBD symptoms had improved or

worsened; if they had had an acute illness or had been out of their usual routine (e.g. on holiday), all of which could impact on psychosocial aspects of eating and drinking and therefore result in a legitimate change in FR-QoL responses. Test-retest reliability was measured by calculating the intra-class correlation and kappa coefficients of FR-QoL sumscores.

RESULTS

Questionnaire development

A total of 148 people with IBD were approached to participate in the questionnaire development and 100 (67.6%) subsequently returned a completed questionnaire. Table 1 summarises the sample characteristics. Mean age of these participants was 43.4 (SD 2.9) years, 46% were female, 64% had a diagnosis of CD, 32% UC and 4% indeterminate IBD. A total of 34% self-reported active disease and 32% had received IBD-related surgery at some point. Demographic characteristics did not differ between responders and non-responders (all $p>0.05$) and the sample was representative of the UK IBD population[47].

A total of 150 potential items were analysed. The proportion of people who responded that an individual item represented an issue that had been important to them in the past two weeks (yes/no) ranged from 0.1 to 0.8. The mean item strength scores ranged between 2.1 (SD 1.5) and 3.8 (SD 1.6) (minimum 1, maximum 5) and the overall importance scores ranged from 0.22 to 2.50. These data informed discussion within the steering group of which items should be retained. A total of 41 items were retained for validation (FR-QoL-41).

Questionnaire validation

A total of 434 IBD patients consented to participate in the questionnaire validation phase, with 323 (74.4%) returning questionnaires, demographic and clinical data for this population are shown in table 2. Missing data for each of the items ranged from 1.2-3.7% and was missing at random. As such, missing data was handled through listwise deletion whereby participants with missing responses were removed from analysis for that questionnaire item.

There were no differences between responders and non-responders in disease type, proportion with moderate/high disease activity (measured via partial Mayo score or Harvey Bradshaw

Index), gender, BMI, MUST nutritional risk score, surgery status or years since diagnosis. However, responders were significantly older (39.2 (SD 15.4) years) than non-responders (37.2 (SD 15.7) years) ($p<0.039$) and were significantly older at diagnosis (28.1 (SD 14.5) years versus 26.4 (SD 15.0) years) ($p<0.001$). Of the 323 patients with IBD, 133 had UC and 190 had CD, the mean BMI was in the healthy range (24.5 kg/m^2) and the majority (78.3%) had a low risk of malnutrition[38]. The mean number of years since diagnosis was 11.0 (SD 10.8) ranging from less than one year to fifty-five years. The sample was representative of the UK IBD population in secondary care[47].

A total of 100 people with asthma and 117 healthy volunteers were recruited as controls. Table 2 shows comparable demographic characteristics across the three groups. The proportion of female participants was significantly lower in the IBD group than both the asthma ($p<0.001$) and healthy volunteer ($p<0.001$) groups, although the latter did not differ from each other. The proportion of current smokers was higher in the IBD group than in the healthy volunteer group ($p=0.06$).

Principle Components Analysis

Individual items were checked for ceiling/floor effects. Less than 5% of respondents scored the highest or lowest possible score on both the initial questionnaire (FR-QoL-41) and the reduced questionnaire (FR-QoL-29).

A Principle Components Analysis (PCA) was carried out on the 41 item questionnaire (FR-QoL-41) to determine the factor structure and identify any redundant items. A total sample of 272 gives a cases-per-predictor ratio of 7:1 which is in keeping with rules of thumb for this type of analysis[48]. The Kaiser-Mayer-Olkin measure of sampling adequacy (KMO=0.95) and Bartlett's test of sphericity ($p<0.001$) met the criteria for performing PCA[49].

The initial PCA showed 7 eigen-values >1 which accounted for 68.4% of the variance, although factors 6 and 7 had eigen values of 1.17 and 1.06 respectively indicating weak factor structures. Items were removed if their factor loading were ≤0.4 as this indicates that the item is not strongly associated with the factor being measured (food-related QoL). In addition, PCA shows how the internal reliability is affected by removing each item. By using an iterative process to remove items that were not strongly and reliably associated with food-related QoL, the questionnaire became more parsimonious. Table 3 shows successive PCA results with the final 29 item questionnaire (FR-QoL-29) having 4 factors and explaining 63.9% of the variance, indicating that the 12 removed items added little to the explained variance and contributed to an unstable factor structure. The final KMO of 0.95, indicates that the FR-QoL-29 has a strong factor structure.

The factor loadings of the FR-QoL-29 are shown in table 4. Factor I appears to measure general food-related QoL as all items have factor loadings ≥0.4. Factor II appears to measure the cognitive and affective aspects of FR-QoL with items referring to concentration, frustration and not knowing which foods will affect symptoms. Factor III refers to the positive aspects of eating and drinking. The fourth factor has only two items with factor loadings ≥0.4, both of which refer to eating foods that triggered symptoms. Although factors II-IV contain items with factor loadings ≥0.4, in all instances these items also load onto factor I with a higher factor loading. For this reason, the FR-QoL-29 is treated as a unidimensional scale measuring general food related QoL and all subsequent analyses use the sumscore of these 29 items.

To ensure that removal of questionnaire items did not compromise the validity and reliability of the FR-QoL questionnaire, analyses were carried out on both the FR-QoL-41 and FR-QoL-

29 versions. The minimum and maximum possible scores for the FR-QoL-41 were 41 and 205 respectively and for the FR-QoL-29 were 29 and 145 respectively.

Internal consistency

The internal consistency was excellent for both the FR-QoL-41 (Cronbach's α=0.962) and the FR-QoL-29 (Cronbach's α=0.959). Removal of the items from the FR-QoL-41 did not impact on the reliability of the scale.

Concurrent Validity

Mean sumscores for the FR-QoL-41 and FR-QoL-29 significantly correlated with sumscores of the IBD-Q[32], HADS[36] and SWFQ[35] in the direction and magnitude that would be expected (table 5). Better food related QoL (higher sumscores on the FR-QoL-29) correlated with better disease-specific quality of life (IBD-Q, r=0.697) and better food satisfaction (SWFL, r=0.701) and correlated negatively with anxiety (HADS-Anxiety subscore, r=-0.531) and depression (HADS-depression subscore, r=-0.519). The strength of the correlation did not differ between these measures and the FR-QoL-41 and the FR-QoL-29.

Discriminant validity

For the IBD group only, patients were dichotomised as having remission/mild or moderate/high disease activity using scores of ≥8 on the Harvey Bradshaw Index for CD[50] and ≥5 for the partial Mayo Score for UC[51]. The FR-QoL-41 successfully discriminated between patients with different disease activity. Therefore, patients with moderate/high disease activity had a significantly lower score (96.9 (SD 29.6)) on the FR-QoL-41 than those with remission/low disease activity (133.8 (SD 35.9); $t_{(265)}=5.56$, $p<0.001$). The same was true for the FR-QoL-29; patients with moderate/high disease activity had a significantly lower score (66.7 (SD 22.1)) compared to those with remission/low disease activity (92.5 (SD

28.1); $t_{(278)}$=5.14. p<0.001). As expected, there were no differences in FR-QoL-29 scores between those with UC or CD ($t_{(283)}$=1.63, p=0.104).

For the FR-QoL-29 sumscores, one-way ANOVA with Bonferroni adjustment between the IBD (N=314), asthma (N=100) and healthy volunteer (N=117) groups was significant ($F_{(2,478)}$ = 101.29, p<0.001), with food-related QoL being significantly lower in patients with IBD (mean=89.5 (SD 28.6)) compared to both the asthma (mean=125.4 (SD 24.1); p<0.001) and healthy control groups (mean=123.0 (SD 16.5); p<0.001) (Figure 1). In contrast, scores of the FR-QoL-29 did not differ significantly between the asthma and healthy control groups (p=1.00) indicating that the questionnaire has excellent discriminant validity. The same pattern of results was found for the FR-QoL-41, as seen in Figure 1.

FIGURE 1 AROUND HERE

Test-retest reliability

Analysis was performed on 63 IBD patients who reported no change in their IBD symptoms in the 4 weeks after completing the first FR-QoL questionnaire. There were no significant differences between demographic characteristics of patients who were and were not included in the analysis. Food-related QoL remained stable over 4 weeks with the correlation between first and second completion for the FR-QoL-41 (r=0.806) and FR-QoL-29 (r=0.833). The intraclass correlation coefficient for the FR-QoL-29 was 0.83 (95% CI=0.76:0.88) indicating good reliability of the measure over time.

DISCUSSION

Recent research has highlighted the importance of psychosocial factors relating to food in the lives of people with IBD[13, 14, 20-23]. Currently, no tool is available to measure the prevalence and magnitude of this issue or to assess the impact of any therapeutic intervention designed to alleviate it. This study aimed to develop and validate a food-related QoL questionnaire for use in both the IBD clinic as well as research trials.

The PCA resulted in a 29 item questionnaire (FR-QoL-29) explaining 63.9% of the variance. The loss of only 4% of the variance and 3 factors after removing 12 items from the FR-QoL-41 indicates that these items were not adequately measuring food-related QoL. The internal consistency of the final FR-QoL-29 was excellent. The factor loading matrix (table 4) shows that all items load highly onto the first factor, suggesting an overall "generic" food-related QoL factor that all items are measuring and as such, the sumscore of the FR-QoL-29 should be used in subsequent studies.

Principle components analysis was used to reduce the number of items in the questionnaire and determine the underlying factor structure. PCA follows classical test theory which assumes that the true score is a combination of the observed (or test) score and the error associated with answering that question. The assumption is that the true and error scores are uncorrelated, i.e. that no one item is more difficult to answer than other (resulting in more error across a sample). We chose to follow classical test theory over the more recently introduced item response theory as the FR-QoL questionnaire is designed to be used in its entirety rather than as individual items and that there is no causal link between the items and the underlying construct, both of which are assumptions of item response theory. Due to the underlying model of classical test theory, it is also possible to use a smaller sample as long as it is representative of the population, which is the case in the current study.

Validity of the questionnaire was tested in a number of ways and was shown to be highly favourable. The FR-QoL-29 had good discriminant validity, suggesting that it is measuring a phenomenon related to living with IBD, rather than simply to experiencing a long term condition. The direction and magnitude of the correlations between the FR-QoL-29 and a number of food-related, generic and disease-specific QoL measures indicated good concurrent validity. The moderate to strong correlations indicate that a construct similar to, but unique from, food satisfaction, disease activity and overall QoL is being measured by the FR-QoL-29.

Previous research indicates that both the nutritional and psychosocial aspects of eating and drinking are important to people with IBD[13, 25]. Family celebrations and religious occasions have been reported as being "no longer joyful" because of food restrictions related to fear of relapse[14, 24], whilst the uncertainty of the impact of eating on bowel function can restrict travel[23] and autonomy due to the perceived need to be near a toilet[14, 24]. The inclusion of items relating to socialising and the cognitive and emotional factors related to eating and drinking in IBD therefore allows for these important constructs to be measured in a valid way for the first time. Generic QoL as measured by the SF-36[37] is known to be lower in long term conditions including IBD than the healthy population[52]. Interventions targeting poor QoL in IBD have so far focused on stress management,[53, 54] however they have ignored the potential stressors around eating and drinking and the use of unmonitored dietary changes as a mechanism for coping with symptoms in IBD[18, 19].

The FR-QoL-29 was stable over time with excellent test re-test reliability in participants who reported no change in their IBD symptoms over four weeks. This, coupled with the significantly lower scores reported by IBD patients compared to controls suggests that food-

related QoL is an important and ongoing issue in IBD, supporting previous qualitative research highlighting this issue[14, 20-23].

No differences in either validity or reliability were found between the FR-QoL-41 and the FR-QoL-29. As the 29 item version is briefer and does not compromise the explained variance, the final version of the questionnaire includes 29 items, measured on a 5 point Likert-type response scale ranging from 1 *(definitely agree)* to 5 *(definitely disagree).*

The questionnaire benefitted from the items being developed directly from verbatim quotes from people with IBD discussing the psychosocial issues around eating and drinking ensuring it is grounded in what is important to IBD patients. The sample of IBD patients in both the development and validation of the questionnaire was large and representative of the outpatient population across the spectrum of disease activity and experience to ensure generalisability. A limitation of the study is that participants in the validation sample completed the entire 41 item version and the items that were subsequently removed could have had priming effects on the answers to the retained items, affecting the scores that were given. Further validation using the final 29 item version should be carried out with confirmatory factor analysis to ensure that the favourable validity and reliability remains.

The FR-QoL-29 questionnaire is a short, self-report questionnaire that has demonstrated good reliability and validity in measuring the psychosocial aspects of eating and drinking in IBD. During this initial development and validation of the questionnaire, it was not possible to establish the responsiveness of the questionnaire to detect a change or to determine the minimal important change[55]. The next steps will be to identify how food-related QoL is related to the patients' clinical condition and the ability of the FR-QoL-29 to detect this, in order to develop an appropriate intervention to address this important but under-acknowledged patient-related outcome.

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Competing interests:

None of the authors have any competing interests to declare.

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References

1. Cohen RD. The quality of life in patients with Crohn's disease. *Aliment Pharmacol Ther* 2002;16:1603-09.
2. Graff LA, Walker JR, Lix L, et al. The relationship of inflammatory bowel disease type and activity to psychological functioning and quality of life. *Clin Gastroenterol. Hepatol*. 2006;4:1491-1501.
3. Ghosh S, Mitchell R. Impact of inflammatory bowel disease on quality of life: results of the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) patient survey. *J Crohns Colitis* 2007;1:10-20.
4. Casellas F, López-Vivancos J, Badia X, et al. Influence of inflammatory bowel disease on different dimensions of quality of life. *Eur J Gastroenterol Hepatol* 2001;13:567-72.
5. Denters MJ, Schreuder M, Depla AC, et al. Patients' perception of colonoscopy: patients with inflammatory bowel disease and irritable bowel syndrome experience the largest burden. *Eur J Gastroenterol Hepatol* 2013;25:964-72.
6. Mowat C, Cole A, Windsor A, et al. Guidelines for the management of inflammatory bowel disease in adults. *Gut* 2011;60:571-607.
7. Norman K, Kirchner H, Lochs H, et al. Malnutrition affects quality of life in gastroenterology patients. *World J Gastroenterol*, 2006;12:3380.
8. Cooper JM, Collier J, James V, et al. Beliefs about personal control and self-management in 30–40 year olds living with inflammatory bowel disease: a qualitative study. *Int J Nurs Stud* 2010;47:1500-09.
9. Prince AC, Moosa A, Lomer MC, et al. Variable access to quality nutrition information regarding inflammatory bowel disease: a survey of patients and health professionals and objective examination of written information. *Health Expect* 2014
10. Inns SJ, Emmanuel AV. Survey of UK and New Zealand gastroenterologists' practice regarding dietary advice and food exclusion in irritable bowel syndrome and inflammatory bowel disease. *Frontline Gastro* 2013;4:44–50.
11. Royal College of Physicians. National audit report of inflammatory bowel disease service provision: adult national report. UK IBD audit. London: RCP, 2014
12. Lomer MC, Gourgey R, Whelan K. Current practice in relation to nutritional assessment and dietary management of enteral nutrition in adults with Crohn's disease. *J Hum Nutr Diet* 2014;27(Suppl 2):28-35.
13. Prince A, Whelan K, Moosa A, et al. Nutritional problems in inflammatory bowel disease: the patient perspective. *J Crohns Colitis* 2011;5:443-50.
14. Hughes LD, Lindsay J, Lomer M, et al. Psychosocial impact of food and nutrition in people with Inflammatory Bowel Disease: A qualitative study. *Gut* 2013;62(Suppl 1): A168.
15. Coveney J. Food, morals and meaning: the pleasures and anxiety of eating. London: Routledge 1999.

16. Gustafsson U, Draper A. The social aspects of food and nutrition. *J Hum Nutr Diet* 2009;22:87-8.
17. Loftus EV. Clinical epidemiology of inflammatory bowel disease: Incidence, prevalence, and environmental influences. *Gastroenterol* 2004;126:1504-17.
18. Cohen AB, Lee D, Long MD, et al. Dietary patterns and self-reported associations of diet with symptoms of inflammatory bowel disease. *Dig Dis Sci* 2013;58:1322-28.
19. Triggs CM, Munday K, Hu R, et al. Dietary factors in chronic inflammation: food tolerances and intolerances of a New Zealand Caucasian Crohn's disease population. *Mutat Res-Fund Mol M* 2010;690:123-38.
20. Fletcher PC, Jamieson AE, Schneider MA, et al. "I Know This Is Bad for Me, But…": A Qualitative Investigation of Women With Irritable Bowel Syndrome and Inflammatory Bowel Disease: Part II. *Clin Nurse Spec* 2008;22:184-91.
21. Fletcher PC, Schneider MA, Van Ravenswaay V, et al. I am doing the best that I can!: Living with inflammatory bowel disease and/or irritable bowel syndrome (part II). *Clin Nurse Spec* 2008;22:278-85.
22. Hall NJ, Rubin GP, Dougall A, et al. The fight for 'health-related normality': a qualitative study of the experiences of individuals living with established inflammatory bowel disease (IBD). *J Health Psychol* 2005;10:443-55.
23. Fletcher PC, Schneider MA. Is There Any Food I Can Eat?: Living With Inflammatory Bowel Disease and/or Irritable Bowel Syndrome. *Clin Nurse Spec* 2006;20:241-247.
24. Daniel JM. Young adults' perceptions of living with chronic inflammatory bowel disease. *Gastroenterol Nurs* 2002;2*5:*83-94.
25. Gray J, Clarke K. "It's all about me". A research project into the role of NACC in addressing the concerns and needs of young people with IBD. Framework 2006.
26. Kurina LM, Goldacre MJ, Yeates D, et al. Depression and anxiety in people with inflammatory bowel disease. *J Epidemiol Community Health* 2001;55:716-20.
27. Nahon S, Lahmek P, Durance C, et al. Risk factors of anxiety and depression in inflammatory bowel disease. *Inflamm Bowel Dis* 2012;1*8:*2086-91.
28. Sandhu A, Mosli M, Yan B, et al. Self-Screening for Malnutrition Risk in Outpatient Inflammatory Bowel Disease Patients Using the Malnutrition Universal Screening Tool (MUST). *JPEN J Parenter Enteral Nutr* 2015;0148607114566656.
29. Guyatt GH, Bombardier C, Tugwell, PX. Measuring disease-specific quality of life in clinical trials. *CMAJ* 1986;134:889-95.
30. Storck AJ, Laupland KB, Read RR,et al. Development of a health-related quality of life questionnaire (HRQL) for patients with extremity soft tissue infections (ESTI). *BMC Infect* Dis 2006;6:148-54.
31. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol* 2007;60:34–42.
32. Cheung WY, Garratt AM, Russell IT, et al. The UK IBDQ—a British version of the inflammatory bowel disease questionnaire: development and validation. *J Clin Epidemiol* 2000;53:297-306.
33. Harvey R, Bradshaw J. A simple index of Crohn's-disease activity. *Lancet.* 1980;1:514.

34. Lewis JD, Chuai S, Nessel L, et al. Use of the noninvasive components of the Mayo score to assess clinical response in ulcerative colitis. *Inflamm Bowel Dis* 2008;14:1660-6.
35. Grunert KG, Dean M, Raats MM, et al. A measure of satisfaction with food-related life. *Appetite* 2007;49:486-93.
36. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;*67:*361-70.
37. Brazier J1, Harper R, Jones NM, et al. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *Bmj* 1992;305:160-4.
38. Malnutrition Advisory Group (MAG) – guidelines for detection and management of malnutrition. British Association for Parenteral and Enteral Nutrition. Redditch, UK 2000.
39. MRC (2000) A Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health. Available at http://www.mrc.ac.uk/documents/pdf/rcts-for-complex-interventions-to-improve-health/
40. Juniper EF, Guyatt GH, Ferrie PJ, et al. Development and validation of a questionnaire to measure asthma control. *Eur Respir J* 1999;14:902-7.
41. Streiner DL, Norman GR, Cairney J. Health measurement scales: a practical guide to their development and use. Oxford university press, UK 2014
42. Joliffe IT, Morgan BJT. Principal component analysis and exploratory factor analysis. *Stat Methods Med Res* 1992;1:69-95.
43. Bland JM, Altman DG. Statistics notes: Cronbach's alpha. *Bmj* 1997;314:572.
44. Hemmerdinger JM, Stoddart SD, Lilford RJ. A systematic review of tests of empathy in medicine. *BMC Med Educ* 2007;7:24.
45. Hattie J, Cooksey RW. Procedures for assessing the validities of tests using the" known-groups" method. *Appl Psychol Meas* 1984;8:295-305.
46. Osterhaus JT, Purcaru O, Richard L. Discriminant validity, responsiveness and reliability of the rheumatoid arthritis-specific Work Productivity Survey (WPS-RA). *Arthritis Res Ther* 2009;11:R73.
47. Royal College of Physicians. National audit report of inflammatory bowel disease service provision: adult national report. UK IBD audit. London: RCP, 2014
48. Tabachnik BGF, Fidell LS. Using Multivariate Statistics. Fifth Edition. New York: Harper Collins 2007.
49. Kaiser H. An index of factorial simplicity. *Psychometrika* 1974;39:31–6.
50. Janssen http://www.janssenmedicalinformation.ca/assets/pdf/HarveyBradshaw_English.pdf Accessed 07.05.15.
51. Colombel JF, Sandborn WJ, Ghosh S, et al. Four-year maintenance treatment with adalimumab in patients with moderately to severely active ulcerative colitis: Data from ULTRA 1, 2, and 3. *Am J Gastroenterol* 2014.
52. Bernklev T, Jahnsen J, Lygren I, et al. Health-related quality of life in patients with inflammatory bowel disease measured with the short form-36: psychometric

assessments and a comparison with general population norms. *Inflamm Bowel Dis* 2005;11:909-18.
53. Keefer L, Doerfler B, Artz C. Optimizing management of Crohn's disease within a project management framework: Results of a pilot study. *Inflamm Bowel Dis* 2012;18:254-60.
54. Thompson RD, Craig A, Crawford EA, et al. Longitudinal results of cognitive behavioral treatment for youths with inflammatory bowel disease and depressive symptoms. *J Clin Psychol Med Settings* 2012;19:329-37.
55. Alrubaiy L, Hutchings HA, Williams JG. Assessing patient reported outcome measures: A practical guide for gastroenterologists. United European Gastroenterol J. 2014;2:463-70.

Table 1: Demographics of patients with IBD involved in the selection of items during the questionnaire development phase

	Total N=100
Disease type, n (%)	
Crohn's disease	64 (64)
Ulcerative Colitis	32 (32)
Indeterminate IBD	4 (4)
Female gender, n (%)	46 (46)
Surgery, n (%)	32 (32)
Self-reported active disease, n (%)	34 (34)
Previous history of dietary treatment for IBD, n (%)	18 (18)
Age, years	
Mean (SD)	40.9 (16.1)
Median (range)	37.0 (17.0-82.0)
Age at diagnosis, years	
Mean (SD)	28.6 (16.2)
Median (range)	24.5 (4.0-79.0)
Years since diagnosis, mean (SD)	17.8 (2.4)
BMI, mean (SD)	24.8 (2.9)

Table 2: Demographics of patients with IBD, asthma and healthy volunteers involved in the questionnaire validation

	Total IBD (N=323)	Ulcerative colitis (N=133)	Crohn's disease (N=190)	Asthma (N=100)	Healthy Volunteers (117)
Gender, n (%)					
Female	163 (50.5)[a,b]	66 (49.6)	97 (51.1)	72 (72)[a]	88 (75.2)[b]
Male	156 (48.5)	66 (49.6)	90 (47.4)	38 (38)	29 (24.8)
Missing	4 (1.2)	1 (0.8)	3 (1.6)	0 (0)	0 (0)
Age					
Mean (SD)	39.2 (15.4)	41.2 (16.4)	37.4 (14.4)	39.2 (15.3)	37.03 (13.8)
Median (range)	35.0 (17-81)	37.0 (17-81)	33.5 (17-78)	37 (17-75)	33 (16.-75)
BMI, kg/m^2					
Mean (SD)	24.5 (4.7)	24.3 (4.5)	24.6 (4.8)	25.0 (6.6)	23.8 (4.0)
Median (range)	23.8 (15.8-43.5)	23.8 (15.8-41.5)	23.8 (16.2-43.5)	24.0 (18.3-43.5)	23.1 (16.9-35.8)
Nutritional risk (MUST), n (%)					
Low risk	253 (78.3)	106 (79.7)	147 (77.4)	-	-
Medium risk	46 (14.2)	15 (11.3)	31 (16.3)	-	-
High risk	24 (7.4)	12 (9.0)	12 (6.3)	-	-
Smoking, n (%)					
Never smoked	179 (55.4)	72 (54.1)	107 (56.3)	70 (70.0)	89 (76.1_
Previously	102 (31.6)	51 (38.3)	51 (26.8)	24 (24.0)	22 (18.8)
Currently	37 (11.5)	9 (6.8)	28 (14.7)	5 (5.0)	6 (5.1)
Missing	5 (1.5)	1 (0.8)	4 (2.1)	1 (1.0)	0 (0.0)
Prior surgery, n (%)					
Yes	110 (34.1)	14 (10.5)	96 (50.5)	-	-
No	210 (65.0)	118 (88.7)	92 (48.4)	-	-
Missing	3 (0.9)	1 (0.8)	2 (1.1)	-	-
Years diagnosed					
Mean (SD)	11.0 (10.8)	9.0 (9.1)	12.3 (11.6)	-	-
Median (range)	8.0 (0.25-55)	6.0 (0.25-45)	10.0 (0.25-55)	-	-
Missing, n (%)	7 (2.2)	3 (2.3)	4 (2.1)	-	-

Age at diagnosis					
Mean (SD)	28.1 (14.5)	31.9 (16.8)	24.4 (12.3)	-	-
Median (range)	24.0 (1.0-80.0)	30.0 (1.0-80.0)	22.0 (6.0-70.7)	-	-

[a,b] $p<0.001$

Table 3: Results of the principle components analysis of the FR-QoL-41 undergoing systematic item removal

Scale	Items removed	KMO	Factors remaining	Variance explained, %	Cronbach's α	Cronbach's α item deleted
FR-QOL-41	-	0.950	7	68.35	0.962	40
FR-QOL-40	40	0.951	7	68.64	0.963	2, 3, 10, 34, 38
FR-QOL-39	10	0.950	7	69.06	0.963	2, 3, 33, 34, 38
FR-QOL-37	12, 20 (healthy eating)	0.952	6	67.51	0.962	2, 3
FR-QOL-35	15, 25 (toilet)	0.951	6	67.75	0.961	-
FR-QOL-34	34	0.952	5	65.39	0.961	-
FR-QOL-33	33	0.952	5	66.00	0.961	-
FR-QOL-32	13	0.952	5	66.15	0.960	2, 3
FR-QOL-31	3	0.951	4	63.79	0.960	2
FR-QOL-30	9	0.950	4	63.72	0.959	-
FR-QOL-29	2	0.949	4	63.93	0.959	-

KMO, Kaiser-Meyer-Olkin measure of sampling adequacy

Table 4: Item factor loadings of the FR-QoL-29 in patients with IBD

In the past two weeks	I	II	III	IV
... I have regretted eating and drinking things which have made my IBD symptoms worse	**.608**	.187	.183	**.514**
... my enjoyment of a particular food or drink has been affected by the knowledge that it might trigger my IBD symptoms	**.659**	-.024	-.034	.371
... my IBD has meant that I have had to leave the table while I am eating to go to the toilet	**.593**	.271	.358	-.206
... I have not been able to predict how long it will take for my body to respond to something I have had to eat or drink due to my IBD	**.599**	.418	-.131	.042
... certain foods have triggered symptoms of my IBD	**.702**	.031	.073	**.458**
... my IBD has meant that I have been nervous that if I eat something I will need to go to the toilet straight away	**.696**	.216	.259	-.106
... I have avoided having food and drink I know does not agree with my IBD	**.543**	**-.424**	-.050	.278
... I have felt relaxed about what I can eat and drink despite my IBD	**.635**	.164	.338	.108
...I have felt in control of what I eat and drink in relation to my IBD	**.580**	.289	.312	.029
... I have struggled to eat the way that is best for my IBD because of other commitments during the day	**.619**	.120	-.108	.148
... I have been frustrated about not knowing how food and drink will react with my IBD	**.653**	**.403**	-.361	.026
... I have had to concentrate on what I have been eating and drinking because of my IBD	**.775**	-.281	-.143	.070
... I have been worried that if I eat I will get symptoms of my IBD	**.771**	.188	.085	.061
... I have felt the way that I eat and drink for my IBD has affected my day to day life	**.789**	-.055	.008	-.170
... the way I have had to eat for my IBD has restricted my lifestyle	**.799**	-.054	.077	-.279

... I have had to concentrate on what food I buy because of my IBD	**.755**	**-.407**	-.076	.025
... it has been on my mind how my IBD will be affected by what I eat and drink	**.816**	-.011	-.186	-.105
... my IBD has prevented me from getting full pleasure from the food and drink I have had	**.817**	-.003	.130	-.100
... I have felt that I need to know what is in the food I am eating due to my IBD	**.670**	-.399	-.080	.001
... I have felt that I have to be careful about when I have eaten because of my IBD	**.800**	-.213	-.025	-.191
...I have had to be more aware of what I am eating due to my IBD	**.796**	-.338	-.19	.044
... I've missed being able to eat or drink whatever I want because of my IBD	**.832**	-.209	-.007	.036
... I have felt that I would like to be able to eat and drink like everyone else	**.771**	-.078	.003	-.056
... I have been happy to eat and drink around people I do not know despite my IBD	**.525**	.117	**.456**	-.246
... I have felt that I have been eating and drinking normally despite my IBD	**.624**	-.091	**.409**	-.008
... I have found it hard not knowing if a certain food will trigger IBD symptoms	**.558**	**.416**	**-.517**	-.006
... my IBD has meant I have had to make an effort to get all the nutrients my body needs	**.489**	-.207	-.352	-.160
... I have felt that I haven't known how my IBD will react to food or drink	**.589**	**.429**	**-.428**	-.095
... my IBD has meant that I have had to work hard to fit my eating habits in around my activities during the day	**.705**	-.040	-.070	-.296

Factor loadings >0.4 appear in bold

Table 5: Correlation between mean sumscores of both the FR-QoL-41 and the FR-QoL-29 and demographic, clinical and quality of life measures in patients with IBD

Correlation with:	**Pearson correlation co-efficient**	
	FR-QoL-41	**FR-QoL-29**
Age	0.122*	0.147*
Gender (0=male, 1=female)	-0.219**	-0.244**
Body mass index (BMI)	0.006	-0.001
Disease type (0=UC, 1=CD)	-0.115	-0.096
Years since diagnosis	0.089	0.105
Surgery (0=no surgery, 1=surgery)	-0.120*	-0.089
Disease activity (0=remission/low, 1=moderate/high)	-0.323**	-0.294**
Food satisfaction (SWFL)	0.736**	0.701**
Anxiety (HADS)	-0.540**	-0.531**
Depression (HADS)	-0.550**	-0.519**
Disease-specific QoL (IBD-Q)	0.731**	0.697**
General QoL (SF-36)	0.554**	0.517
SF36 physical functioning	0.424**	0.392**
SF36 role limitation-physical	0.495**	0.475**
SF36 role limitation-emotional	0.464**	0.453**
SF36 energy/fatigue	0.512**	0.499**
SF36 emotional wellbeing	0.461**	0.445**
SF36 social functioning	0.536**	0.511**
SF36 pain	0.511**	0.482**

*p<0.05; **p<0.001

Figure Legends:

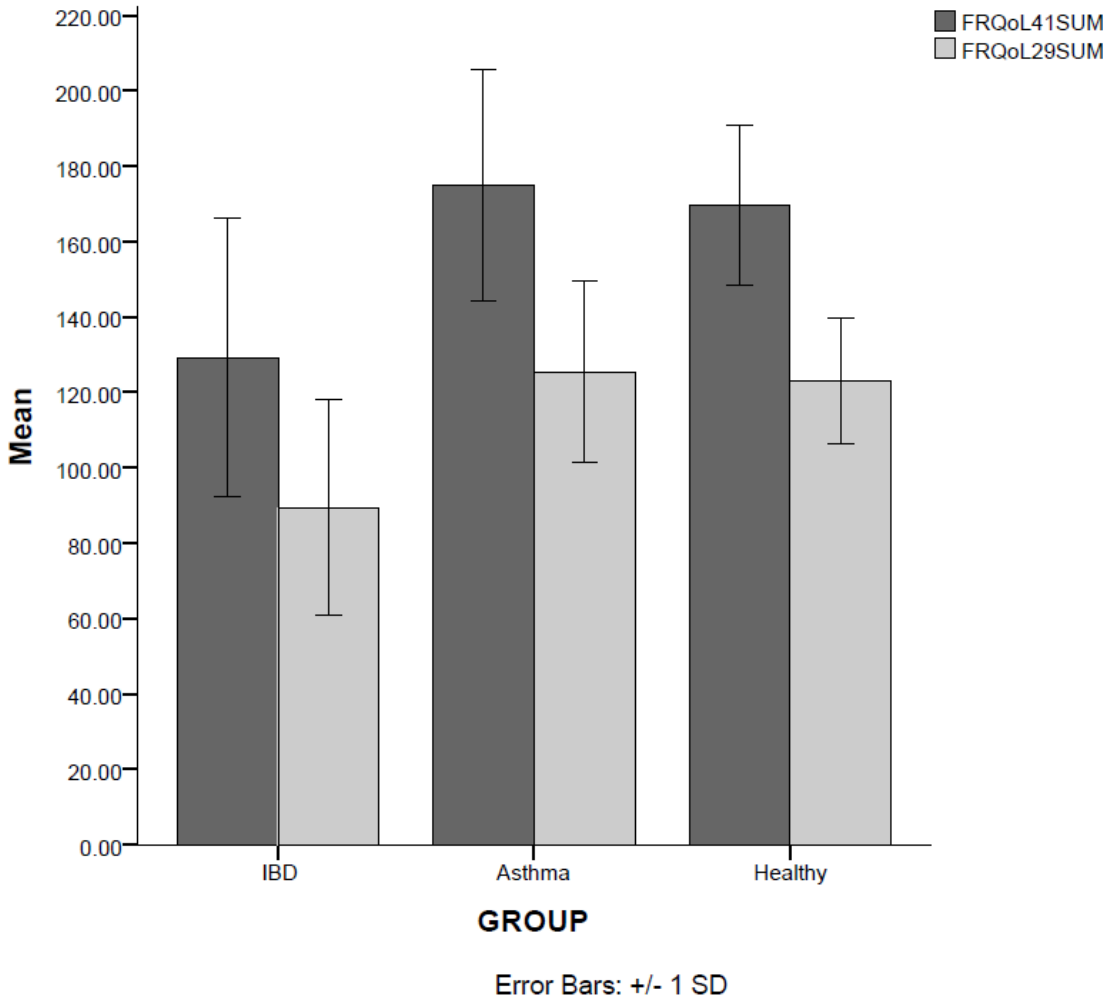

Figure 1: Mean (SD) food-related quality of life sumscores for patients with IBD, asthma and healthy volunteers.

Values are mean sumscores for the FR-QoL-41 (dark grey) and the FR-QoL-29 (light grey) comparing patients with IBD (N=314), asthma (N=100) and healthy volunteers (N=117). Error bars are +/- 1 SD. One-way ANOVA with Bonferroni adjustment indicates lower scores for FR-QoL-29 in patients with IBD (mean=89.5, SD 28.6) compared to asthma (mean=125.4, SD 24.1; $p<0.001$) and healthy volunteers (mean=123.0, SD 16.5; $p<0.001$).